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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,702	02/13/2001	Raymond F. Cracauer	FORS-06111	4955

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/782,702	CRACAUER, RAYMOND F.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,22-25 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 22-25 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 11 August 2003 in which the specification was amended to cross-reference the parent application and to add "DESCRIPTION OF THE FIGURES". All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 6 May 2003 are maintained and reiterated below. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 1-16, 22-25 and 36-44 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-16, 22-25, 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLuen et al (WO 99/65602, published 23 December 1999) in view of Zuckermann et al (WO 98/10857, published 19 March 1998).

Regarding Claim 1, McLuen et al teach a cartridge comprising a plurality of receiving holes configured to hold nucleic acid synthesis columns, wherein the cartridge is further configured to receive the columns forming a seal between the holes and columns (page 12, lines 4-23) which clearly suggests that a seal between the holes and columns are required.

McLuen et al do not specifically teach that the cartridge is configured to receive one or more o-rings to provide the seal between the columns and holes. However, cartridges configured to receive o-rings thereby providing a seal between holes and columns were well known in the art at the time the claimed invention was made as taught by Zuckermann et al.

Zuckermann et al teach a similar cartridge comprising a plurality of receiving holes configured to hold nucleic acid synthesis columns, wherein the cartridge is further configured to receive an o-ring (i.e. annular sealing means) whereby a seal is formed between the holes and columns(page 3, lines 9-29). Furthermore, they teach that the o-ring facilitates sealing between the holes and column (page 11, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge configuration of McLuen et al by configuring the cartridge to receive o-rings between the holes and columns thereby facilitating a tight seal between the holes and columns as taught by Zuckermann et al (page 7, lines 1-10 and page 11, lines 9-29). One of ordinary skill in the art would have been motivated to facilitate the tight seal based on the teaching of McLuen et al wherein a tight seal is desired (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 2, McLuen et al teach a nucleic acid synthesis system containing a cartridge as defined in Claim 1 (page 1, lines 5-7 and Fig. 1).

Regarding Claim 3, McLuen et al teach the cartridge wherein said plurality of holes comprises 12 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 4, McLuen et al teach the cartridge wherein said plurality of holes comprises 48 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 5, McLuen et al teach the cartridge is configured to receive the gasket i.e. the cartridge is configured to such that "support" (Fig. 6 #660) fits within the receiving hole to form a tight seal. McLuen et al do not specifically teach that the gasket provides one or more o-rings. However, gaskets providing o-rings and thereby providing a seal between holes

and columns were well known in the art at the time the claimed invention was made as taught by Zuckermann et al.

Zuckermann et al teach the similar cartridge wherein the cartridge is further configured to receive a gasket (i.e. mating notch, Fig. 3, #152) and o-ring (i.e. annular sealing means, Fig. 3, #150) whereby a seal is formed between the holes and columns (page 3, lines 9-29). Furthermore, they teach that the gasket/ o-ring (mating notch/annular sealing means) facilitate sealing between the holes and column (page 11, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge configuration of McLuen et al by configuring the cartridge to receive the gasket and o-rings between the holes and columns thereby facilitating a tight seal between the holes and columns as taught by Zuckermann et al (page 11, lines 9-29). One of ordinary skill in the art would have been motivated to facilitate the tight seal based on the teaching of McLuen et al wherein a tight seal is desired (page 12, lines 19-23).

Regarding Claim 6, McLuen et al teach the cartridge wherein the plurality of holes comprise an upper portion and a lower portion wherein the lower portion comprises a first diameter and the upper portion comprises a diameter larger than the first diameter i.e. the receiving holes have a "precise diameter" corresponding to the exterior dimension of the vials (page 7, lines 7-10) which have an upper diameter that is larger than the lower diameter (Fig. 6).

Regarding Claim 7, McLuen et al teach the cartridge wherein the plurality of holes comprise an upper portion with a first diameter and a middle portion with a second diameter and a lower portion with a third diameter wherein the second diameter is larger than the first diameter and the first diameter is larger than the third diameter i.e. the receiving holes have a "precise diameter" corresponding to the exterior dimension of the vials (page 7, lines 7-10) which have an upper diameter that is larger than the lower diameter (Fig. 6).

Regarding Claim 8, McLuen et al teach the cartridge wherein the middle portion is configured to tightly seal with the column (page 7, lines 7-10) but they do not teach the cartridge is configured to hold an o-ring. However, as stated above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of McLuen et al by configuring the cartridge to hold an o-ring to thereby facilitate providing a tight seal between the columns and holes as taught by Zuckermann et al based on the fact that McLuen et al desires a tight seal (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 9, McLuen et al teach a system comprising an open system nucleic acid synthesis cartridge comprising at least one receiving hole configured to receive a nucleic acid synthesis column. McLuen et al do not specifically teach that the cartridge is configured to receive one or more o-rings to provide the seal between the columns and holes. However, cartridges configured to receive o-rings thereby providing a seal between holes and columns were well known in the art at the time the claimed invention was made as taught by Zuckermann et al.

Zuckermann et al teach a similar cartridge comprising a plurality of receiving holes configured to hold nucleic acid synthesis columns, wherein the cartridge is further configured to receive an o-ring (i.e. annular sealing means) whereby a seal is formed between the holes and columns(page 3, lines 9-29). Furthermore, they teach that the o-ring facilitates sealing between the holes and column (page 11, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge configuration of McLuen et al by configuring the cartridge to receive o-rings between the holes and columns thereby facilitating a tight seal between the holes and columns as taught by Zuckermann et al (page 7, lines 1-10 and page 11, lines 9-29). One of ordinary skill in the art would have been motivated to facilitate the tight seal based on the teaching of McLuen et al wherein a tight seal is desired (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 10, McLuen et al teach the system wherein the cartridge is comprises a rotary cartridge (page 5, lines 5-14 and page 6, line 24-page 7, line 17).

Regarding Claims 11-12, McLuen et al teach the system wherein a tight seal between the receiving hole and column is desired (page 7, lines 7-10 and page 12, lines 19-23) but they do not teach the cartridge is configured to hold an o-ring. However, as stated above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of McLuen et al by configuring the cartridge to hold an o-ring to thereby facilitate providing a tight seal between the columns and holes as taught by Zuckermann et al based on the fact that McLuen et al desires a tight seal (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 13, McLuen et al teach the cartridge comprises a plurality of receiving holes (page 7, lines 11-17 and Fig. 3).

Regarding Claim 14, McLuen et al teach that a tight seal between the receiving holes and column is desired (page 7, lines 7-10 and page 12, lines 19-23) but they do not teach the cartridge is configured to hold an o-ring. However, as stated above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of McLuen et al by configuring the cartridge to hold an o-ring to thereby facilitate providing a tight seal between the columns and holes as taught by Zuckermann et al based on the fact that McLuen et al desires a tight seal (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 15, McLuen et al teach the cartridge wherein said plurality of holes comprises 12 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 16, McLuen et al teach the cartridge wherein said plurality of holes comprises 48 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 22, McLuen et al teach the synthesis system of Claim 2 further comprising a reagent dispensing station configured to house one or more reagent reservoirs such that reagents can be delivered to the cartridge (page 5, lines 5-31 and Fig. 1).

Regarding Claim 23, McLuen et al teach the synthesis system wherein said dispensing station comprises a ventilation tube configured to remove gaseous emissions form the dispensing station (page 10, lines 6-13).

Regarding Claim 24, McLuen et al teach the system wherein the dispensing station comprises an enclosure i.e. reservoirs within the base (page 5, lines 5-6 and 15-16).

Regarding Claim 25, McLean et al teach the system wherein the dispensing station comprises a viewing window configured to allow visual inspection of the reagent reservoirs (page 9, line 30-page 10, line 5).

Regarding Claim 36, McLuen et al teach the system of Claim 11 further comprising a synthesis and purge component in a pressurizable chamber wherein said seal between the receiving hole and column is configured to maintain pressure in the chamber during purging (page 10, lines 18-23).

Regarding Claim 37, McLuen et al teach the cartridge comprises a plurality of receiving holes (page 7, lines 11-17 and Fig. 3).

Regarding Claim 38, McLuen et al teach that a tight seal between the receiving holes and column is desired (page 7, lines 7-10 and page 12, lines 19-23) but they do not teach the cartridge is configured to hold an o-ring. However, as stated above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of McLuen et al by configuring the cartridge to hold an o-ring to thereby facilitate providing a tight seal between the columns and holes as taught by Zuckermann et al based on the fact that McLuen et al desires a tight seal (page 7, lines 7-10 and page 12, lines 19-23).

Regarding Claim 39, McLuen et al teach the cartridge wherein said plurality of holes comprises 12 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 40, McLuen et al teach the cartridge wherein said plurality of holes comprises 48 or more (page 7, lines 11-17 and Fig. 3).

Regarding Claim 41, McLuen et al teach the synthesis system of Claim 2 further comprising a reagent dispensing station configured to house one or more reagent reservoirs such that reagents can be delivered to the cartridge (page 5, lines 5-31 and Fig. 1).

Regarding Claim 42, McLuen et al teach the synthesis system wherein said dispensing station comprises a ventilation tube configured to remove gaseous emissions form the dispensing station (page 10, lines 6-13).

Regarding Claim 43, McLuen et al teach the system wherein the dispensing station comprises an enclosure i.e. reservoirs within the base (page 5, lines 5-6 and 15-16).

Regarding Claim 44, McLean et al teach the system wherein the dispensing station comprises a viewing window configured to allow visual inspection of the reagent reservoirs (page 9, line 30-page 10, line 5)

Response to Arguments

4. Applicant argues that the Office has not met the burden of establishing a prima facie case of obviousness because the cited references do not teach all of the elements of the claimed invention and because there is no motivation to combine the cited art. These two issues are discussed in response to Applicant's specific comments detailed below.

Specifically, Applicant argues that the instant invention is drawn to a cartridge configured to receive one or more O-rings and further configured to hold a DNA synthesis column, but neither McLuen et al nor Zuckermann et al teach this configuration. The argument has been considered but is not found persuasive because, as Applicant acknowledges, the instant claims are drawn to a cartridge the cartridge is configured to hold synthesis columns and to receive one or more O-rings. The cartridge is not limited to synthesis columns and/or O-rings, but is merely configured so as to hold the columns and O-rings. As stated above, McLuen et al teach a cartridge configured to hold DNA synthesis columns wherein the cartridge is further configured to receive the columns forming a seal between the holes and columns (page 12, lines 4-23) which clearly suggests that a seal between the holes and columns are required. McLuen et al do not specifically teach that the cartridge is configured to receive one or more o-rings to provide that desired seal. However, cartridges configured to receive o-rings thereby providing a seal between holes and columns were well known in the art at the time the claimed invention was made as taught by Zuckermann et al.

who further teach that the o-ring facilitates sealing between the holes and column (page 11, lines 19-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge configuration of McLuen et al by configuring the cartridge to receive o-rings between the holes and columns thereby facilitating a tight seal between the holes and columns as taught by Zuckermann et al (page 7, lines 1-10 and page 11, lines 9-29). One of ordinary skill in the art would have been motivated to facilitate the tight seal based on the teaching of McLuen et al wherein a tight seal is desired (page 7, lines 7-10 and page 12, lines 19-23).

Applicant argues that there is no motivation to combine the teachings of Zuckermann et al and McLuen et al and further argues that the Office has failed to explain why one of ordinary skill in the art would have been motivated to combine these references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, in contrast to Applicant's assertion, the Office has cited motivation found within the teaching of Zuckermann et al for modifying the teaching of McLuen et al with the teaching of Zuckermann et al i.e. McLuen et al desire a seal between the between the holes and columns (page 12, lines 4-23) and Zuckermann et al. further teach that the o-ring facilitates sealing between the holes and column (page 11, lines 19-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge configuration of McLuen et al by configuring the cartridge to receive o-rings between the holes and columns thereby facilitating a tight seal between the holes and columns as taught by Zuckermann et al (page 7, lines 1-10 and page 11, lines 9-29). One of ordinary skill in the art would have been motivated to facilitate the tight seal based on the teaching of McLuen et al wherein a tight seal is desired (page 7, lines 7-10 and page 12, lines 19-23).

Applicant argues that McLuen et al do not identify a problem with forming a seal and therefore one in the art would not have been motivated to modify their cartridge. The argument has been considered but is not found persuasive for the reasons stated above i.e. McLuen et al is silent regarding any means for providing a seal between the column and cartridge, but clearly desires a seal (page 12, lines 4-23) and Zuckermann et al. further teach that the o-ring

facilitates sealing between the holes and column (page 11, lines 19-24). As such, the Office has properly relied on teachings found in the cited references to provide a prima facie case of obviousness.

Finally, Applicant argues that Zuckermann et al do not teach or suggest a cartridge comprising a plurality of receiving holes configured to hold nucleic acid synthesis columns wherein the cartridge is further configured to receive an O-ring and therefore Zuckermann et al do not teach methods relevant to the claimed methods for forming a seal between the receiving hole of a cartridge and the reaction vessel. The argument has been considered but is not found persuasive because the claims are drawn to a cartridge configured to receive a synthesis column and an o-ring. As such, arguments regarding methods for forming a seal are not commensurate in scope with the instant claims. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 7, 2003